



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,105	02/13/2002	Zhijian T. Li	72978	6947

22242 7590 10/19/2005

FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,105

Applicant(s)

LI ET AL.

Examiner

Celine X. Qian Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-17, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 18, 19, 22 and 23 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0602,0203</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-23 are pending in the application.

Election/Restrictions

Applicant's election of Group I in the reply filed on 8/17/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, the response is not complete because Applicants fail to elect one specific sequence as required in the action mailed on 7/14/05. During a telephone conversation with Applicant's representative Mr. Krueger on 10/6/05, a provisional election was made without traverse to prosecute the invention of Group I, and sequences directed to SEQ ID NO:1. Affirmation of this election must be made by applicant in replying to this Office action.

Accordingly, claims 10-17, 20 and 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-9, 18, 19, 22 and 23 are currently under examination on merits.

Claim Objections

Claim 9 is objected to for containing non-elected subject matter. The claim recites both SEQ ID NO:1 and SEQ ID NO:2. However, SEQ ID NO:2 is not elected subject matter. Amending the claims such that they are only directed to elected inventions is required.

Claim 9 is also objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The word “about” renders the claim indefinite because it is unclear what percentage is encompassed by the term “about 30%.” In other words, is “25%, 35%, 40%” considered “about 30%?”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 18, 19, 22 and 23 are rejected under 35 U.S.C. 102(b) and (e) as being anticipated by Hobart et al (US 5,891,718).

The claims are drawn to a bidirectional promoter complex comprising: a modified enhancer region that includes at least two enhancer sequences; and at least two core promoters, the core promoter being on either side of the modified enhancer. The claims are further drawn to

Art Unit: 1636

such a bidirectional promoter complex wherein the modified enhancer region includes at least two tandem oriented enhancer sequence having substantial sequence identify, wherein enhancer is linked in a 5-3 orientation, wherein the number of enhancer is a multiple of two, wherein the two promoter have a sequence homology about 30% and include at least 5 base pair of identical contiguous nucleotides, wherein the promoter is fused to either end of the enhancer, wherein the promoter comprises a TATA-box consensus element and an initiator, or wherein the core promoter further comprises at least one cis-acting element. The claims are further drawn to a vector comprises said promoter and a eukaryotic cell transfected with said vector. The claims are also drawn to a method of improving transcription efficiency or producing polypeptide by inserting a transgene into a vector comprising said bidirectional vector.

Hobart et al. disclose a vector (UR1375, see Figure 7) comprising a bidirectional promoter that comprises seven copies of tandem tetOperator sequence (tet activator sequence), a CMV enhancer, and two core CMV IE promoter which comprises TATA box in a divergent orientation. Hobart et al. further disclose that this vector is introduced into C2C12 cell line (see col.18, lines 23-33). Hobart et al. also disclose that reporter genes are inserted downstream to the bidirectional vector and expressed in cells transfected with said vector (see col. 17, bridging paragraph to col. 18). Seven copies of tet activator sequence plus one CMV enhancer is a multiple of two. The 5' UTR and intron A of CMV IE inherently comprises cis-regulatory element. Therefore, Hobart et al. disclose the instantly claimed inventions.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER

